A14475 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: August 17, 2010

UMDNS Terms:
- Infusion Pump Administration Sets [16579]
- Infusion Pumps, Patient-Controlled Analgesic [16924]

Suggested Distribution:
- Anesthesia
- Critical Care
- Nursing
- Home Care
- Pain Clinic
- IV Therapy
- Materials Management

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- U.S.

Hospira—GemStar Infusion Pump Sets: Underdelivery May Occur

Product Identifier:

GemStar Infusion Pump Products:	List Nos.:	Lot Nos.:
(1) Pump Sets	(1) 12640-01	(1) 682105H, 770815H
	(1) 13261-01	(1) 670695H, 691805H, 760666H, 772085H
	(1) 19680-28	(1) 772075H
	(1) 20634-01	(1) 682085H
(2) Pump Sets with Convertible Pin	(2) 20635-01	(2) 691825H, 701295H, 781565H
(3) Secure Lock Pump Sets	(3) 13263-01	(3) 682095H
	(3) 13273-01	(3) 680295H, 770875H

[Consumable, Capital Equipment]

Units distributed between September 2008 and June 2010

Manufacturer: Hospira Inc [440680], 275 N Field Dr, Lake Forest, IL 60045, United States

Problem: In an August 12, 2010, Urgent Device Recall letter submitted by an ECRI Institute member hospital, Hospira states that it has received reports of underdelivery during clinical use of the above pump sets. This problem may occur under rate settings of <10 mL/hr. Hospira also states that it has received no reports of adverse events related to this problem. The manufacturer has not confirmed the information provided in the source material.

Manufacturer:	Designation:
Hospira	Reference No. FA007-01

Action Needed: Verify that you have received the August 12, 2010, Urgent Device Recall letter and reply form from Hospira. Identify, isolate, and discontinue use of any affected product in your inventory. Regardless of whether you have affected product, complete the reply form and return it to Stericycle by fax at (877) 523-9110 within the U.S. or using the instructions on the form outside the U.S. Inform all relevant personnel at your facility of the information in the Urgent Device Recall letter. Forward a copy of the letter to any facility to which you may have further distributed affected product.

For Further Information:			
Geographic Location:	Contact:	Telephone No.:	Web Site:
U.S.	For medical	(800)	Click here

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	inquiries: Hospira medical communications	615-0187	
	For product return inquiries: Stericycle	(877) 274-7163	
Outside the U.S.	Hospira local representative		

Source:

- Letter submitted by ECRI Institute member hospital.

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.

This alert is based on information that may not be independently verified as to its accuracy, completeness, or causal relationship to the product or its supplier.

- The manufacturer has not confirmed the geographic distribution of affected product. ECRI Institute recommends that you check your inventory for this product regardless of where you are located.

Verification History: One Member Submission[8/17/2010 2:04:50 PM]

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